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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:)
)
Jeong S. Lee, et al.)
)
Serial No.: 09/470,009)
)
Filed: December 22, 1999)
)
For: NON-METAL REINFORCING MANDREL)

Examiner: LAM, Ann Y.

Art Unit: 3763

Commissioner for Patents
U. S. Patent and Trademark Office
Washington, D.C. 20231

APPEAL BRIEF
IN SUPPORT OF APPELLANT'S APPEAL
TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Dear Sir:

Appellant hereby submits this Brief in triplicate in support of an appeal from a final decision by the Examiner, mailed on September 25, 2002, in the above-captioned case. Appellant respectfully requests consideration of this appeal by the Board of Patent Appeals and Interferences for allowance of the above-captioned patent application.

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TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is Advanced Cardiovascular Systems, Inc. of Santa Clara, California, U.S.A.

II. RELATED APPEALS AND INTERFERENCES

To the best of Appellant's knowledge, there are no appeals or interferences related to the present appeal which will directly affect, be directly affected by, or have a bearing on the Board's decision.

III. STATUS OF CLAIMS

For the purposes of this appeal, claims 11 – 26 and 39 – 56 stand rejected. New dependent claims 57 – 66 have been added. A copy of claims 11 – 26 and 39 – 56 is attached as Appendix A. A copy of new claims 57 – 66 is attached as Appendix B.

IV. STATUS OF AMENDMENTS

New claims 57 – 66 have been added to better define and clarify the present invention. The new claims are supported by the specification, and no new matter has been added. These new claims 57 – 66 have NOT been entered.

V. SUMMARY OF THE INVENTION

The invention defined in the appealed claims concerns an apparatus for providing support for a catheter. An embodiment of the present invention includes a mandrel disposed within a dilatation catheter (p. 7, lines 17 – 24, and Figures 1A and 1B). The catheter has an inner tubular member with an inner lumen adapted to receive a guidewire. As such, the mandrel is independent of a guidewire. An outer tubular member is disposed about the inner tubular member, and the mandrel is typically between the inner and outer tubular members. The mandrel of the present invention is fabricated from a non-metal material. The non-metal mandrel may be more compatible with the standard materials used for a catheter shaft. This compatibility between the mandrel and the catheter shaft allows the mandrel to be fused to the shaft in certain embodiments. This locks the mandrel in place and makes the external force and support to be applied more efficiently (p. 9, lines 14 – 22).

VI. ISSUES

A. Whether claims 11, 13, 16-18, 39, 42-45, 48-51 and 54-56 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,147,317 of Shank et al. ("Shank").

B. Whether claim 12 is unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,950,257 of Hibbs et al. ("Hibbs").

C. Whether claims 11 – 26 and 39 – 56 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,246,420 of Kraus et al. ("Kraus") in view of U.S. Patent 5,836,892 of Lorenzo ("Lorenzo").

VII. GROUPING OF CLAIMS

With regard to the ground of rejection stated in issue A, claims 11, 13, 16-18, 39, 42-45, 48-51 and 54-56 stand or fall together.

With regard to the ground of rejection stated in issue C, claims 11 – 26 and 39 – 56 stand or fall together.

VIII. ARGUMENTS

A. Claims 11, 13, 16-18, 39, 42-45, 48-51 and 54-56 are not unpatentable under 35 U.S.C. § 102(b) as being anticipated by Shank.

The Examiner rejected claims 11, 13, 16 – 18, 39, 42-45, 48 – 51 and 54 – 56 under 35 § U.S.C. 102(b) as being anticipated by Shank.

Shank discloses a guidewire for use in the placement of a catheter. In the Background of the Invention, Shank discloses guidewires in the context of percutaneous transluminal coronary angioplasty ("PTCA") procedures, in which a catheter is advanced over the guidewire to guide the catheter to the obstruction site. (Shank, col. 1, lines 45 – 52). The guidewire includes an elongate flexible core wire and a helical coil wrapped about the core wire. (Shank, col. 4, lines 20 – 40, and Figure 1). This guidewire construction reduces the area of contact between the guidewire and the inner surface of the catheter with which the guidewire will be used, which may lessen resistance to guidewire movement within the catheter lumen. (Shank, col. 7, lines 19 – 27). Shank also teaches the core wire is preferably formed from stainless steel or other suitable flexible, straight, strong material. (Shank, col. 4, lines 23 – 25).

Appellant respectfully submits that Shank does not teach or disclose the present invention as claimed. Independent claims 11, 39, 45, and 51 provide for a catheter that is reinforced by a mandrel. Appellant submits that a mandrel is not equivalent to a guidewire. As discussed in Background section of Shank, a guidewire is independent of the catheter in which the catheter is advanced over the guidewire. In other words, the catheter moves relative to the stationary guidewire. In contrast, Appellant discloses supporting the catheter of one embodiment more efficiently by fusing or locking the mandrel to a catheter shaft, which would result in the mandrel moving with the catheter when advanced over a guidewire (see, for example, p. 9, lines 19 – 22 of the present invention). New dependent claims 57, 61, 63, and 65 include the limitation of the mandrel fixed to the catheter or catheter shaft. There is no teaching or suggestion in Shank of fixing the mandrel to the catheter or catheter shaft. Furthermore, new dependent claims 58, 62, 64, and 66 include the limitation of an inner tubular member adapted to receive a guidewire, from demonstrating that the mandrel is separate from a guidewire.

Shank also fails to teach a mandrel that is made of a non-metal material. Appellant submits that, in contrast, independent claims 11, 39, 45, and 51 provide for a non-metal material mandrel. As a matter of fact, Shank expressly teaches away from a guidewire that is made of a non-metal material. As discussed above, Shank teaches that the guidewire is preferably formed from stainless steel.

With respect to claim 39, a further limitation is also included. The mandrel is formed by necking at high temperatures such that the proximal section is stiffer than the distal section. Although Shank teaches that the distal portion of the guidewire may have

a reduced diameter and be more flexible than the proximal portion, it fails to teach the process of necking to produce that property.

With respect to claim 45, a different additional limitation is included. The mandrel is formed by annealing to induce higher crystallinity such that the proximal section is stiffer than the distal section. Although Shank teaches that the distal portion of the guidewire may have a reduced diameter and be more flexible than the proximal portion, it fails to teach annealing to produce that property.

With respect to claim 51, yet another additional limitation is included. The mandrel is formed by taper extruding such that the proximal section is stiffer than the distal section. Although Shank teaches that the distal portion of the guidewire may have a reduced diameter and be more flexible than the proximal portion, it fails to teach the technique of taper extruding to produce that property.

B. Claim 12 is not unpatentable under 35 U.S.C. § 102(b) as being anticipated by Hibbs.

The Examiner rejected claim 12 under 35 § U.S.C. 102(b) as being anticipated by Hibbs. Claim 12 depends from and includes all the limitations of independent claim 11. The Examiner contends that Hibbs discloses a mandrel comprised of a variable stiffness, non-metal material. (Office Action dated 03/29/02, page 5, lines 6 – 10). Appellant respectfully submits that Hibbs actually discloses an introducer system for insertion over a guidewire. The body 24 and tip 26 of the introducer form a sheath which, after removal of the guidewire and dilator, provides a sealed and protected pathway for a catheter into a blood vessel. (Hibbs, col. 3, lines 45 – 60, and Figures 1 & 2).

Appellant respectfully submits that the sheath disclosed in Hibbs is not equivalent to a mandrel as claimed. The sheath of Hibbs is structured to receive either a guidewire or catheter. In other words, the sheath of Hibbs remains fixed as either a guidewire or catheter moves relative to it. In contrast, Appellant discloses supporting the catheter of one embodiment more efficiently by fusing or locking the mandrel to a catheter shaft, which would result in the mandrel moving with the catheter when advanced over a guidewire (see, for example, p. 9, lines 19 – 22 of the present invention). New dependent claim 57 includes the limitation of the mandrel fixed to the catheter or catheter shaft. There is no teaching or suggestion in Hibbs of fixing the mandrel to the catheter or catheter shaft. As such, Appellant respectfully submits that Examiner's assertion that catheter portions may be made of polyamide material is moot.

C. Claims 11 – 26 and 39 – 56 are not unpatentable under 35 U.S.C. § 103(a) as being unpatentable over Kraus in view of Lorenzo.

The Examiner rejected claims 11 – 26 and 39 – 56 under 35 U.S.C. § 103(a) as being unpatentable over Kraus in view of Lorenzo. Kraus discloses a catheter that includes a balloon 10, a guidewire with a tapered mandrel 11, an outer catheter shaft of tube 14, and a proximal adapter 15. The distal end of the guidewire passes through two tubular elements 21, 22 inside the outer catheter tube 14 and the balloon 10, and terminates in a tip coil 12 emerging from the catheter end. The tubular elements provide column support for the balloon. (Kraus, col. 7, lines 54 – 62, and Figure 1). As discussed in the Background of the Invention section, the catheter of Klaus is directed towards non-over-the-wire systems in which the guidewire components are permanently

held inside the respective catheter tube and balloon components. (Kraus, col. 3, lines 1 – 10). Kraus fails to teach or suggest a catheter having both mandrel and guidewire separately. Kraus also teaches that the guidewire component consists of a length of stainless steel hypodermic needle tubing. (Kraus, col. 14, lines 16 – 19). Lorenzo discloses a guidewire a tip section of a guidewire 12 having radiopaque markers 14. The radiopaque markers are spaced apart by polyimide tubing segments 31 – 37 mounted on a stainless steel core wire 40. However, the guidewire is stainless steel. (Lorenzo, col. 2, lines 20 – 30, and Figure 1). Nothing in Lorenzo teaches or suggests a mandrel made of non-metal material.

First, Appellant submits that there is no motivation or suggestion for combination of the cited references. The Office Action states that "it would have been obvious to a person of ordinary skill in the art at the time the invention was made to form the Kraus mandrel from polyimide material, as taught by Lorenzo, as known material used to form mandrels." (Office Action, 03/29/02, page 7). Here, the Office Action merely states an advantage of substituting the guidewire (i.e., a guidewire with tubing segments) of Lorenzo, with the guidewire of Kraus, without explaining what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination. As discussed above, the mandrel of embodiments of the present invention is part of a catheter, and this mandrel is separate from a guidewire (clarified by new dependent claims 58, 60, 62, 64, and 66). As such, the Examiner has not provided a motivation to combine any references to produce a catheter having both a reinforcing mandrel and a guidewire separately.

Second, one of ordinary skill in the art would not be motivated to combine Kraus and Lorenzo because Kraus teaches away from over-the-wire devices and instead focuses on non-over-the-wire systems, as discussed above. In contrast, Lorenzo fails to teach or suggest non-over-the-wire systems and focuses only on the guidewire itself. Because of the very different nature of non-over-the-wire systems compared to over-the-wire systems, Appellant respectfully submits that one of ordinary skill in the art in non-over-the-wire systems would look towards over-the-wire systems, and vice versa.

Even if Kraus and Lorenzo were combined, it would still not result in the present invention as claimed. First, combining the guidewire from Lorenzo with the catheter of Kraus would not result in a non-metal material mandrel because both references teach and suggest stainless steel guidewires only. Second, the guidewire of Lorenzo could not operate practically with the non-over-the-wire catheter of Kraus, because the catheter of Kraus already has a guidewire within it. Even if the catheter of Kraus could be adapted to receive two guidewires, it would still not result in the invention as claimed. Third, substituting the guidewire from Lorenzo with the guidewire from Kraus would not teach a catheter having both a mandrel and guidewire separately (further clarified by new dependent claims 58, 60, 62, 64, and 66). Fourth, both Kraus and Lorenzo, either alone or in combination, fails to teach or suggest the additional limitations provided in independent claims 39, 45, and 51. Fifth, both Kraus and Lorenzo, either alone or in combination, fails to teach or suggest the independent claim 19 limitation of an outer lumen between the inner and outer members, with the mandrel extending through the outer lumen.

IX. CONCLUSION

For the foregoing reasons, Appellant respectfully asserts that claims 11, 13, 16 – 18, 39, 42-45, 48 – 51 and 54 – 56 are not unpatentable under 35 § U.S.C. 102(b) as being anticipated by Shank, and claim 12 as being anticipated by Hibbs. Appellant also respectfully asserts that claims 11 – 26 and 39 – 56 are not unpatentable under 35 § U.S.C. 103(a) over Kraus in view of Lorenzo. Any dependent claims not specifically addressed are deemed allowable in view of its dependency from an independent claim as argued above. For the reasons presented herein, Appellant respectfully requests removal of the present rejections and allowance of the present claims.

Fee For Filing Notice of Appeal

A check in the amount of $320.00 to cover the fee for filing a Notice of Appeal required under 37 C.F.R. 1.17(b) was previously submitted with a prior Notice of Appeal on December 24, 2002.

Fee For Filing a Brief In Support of Appeal

Enclosed is a check in the amount of $320.00 to cover the fee for filing of a brief in support of an appeal required under 37 C.F.R 1.17 (c) and 1.192. This Brief is filed within two months of receipt of the filed Notice of Appeal dated December 30, 2002.

Charge Our Deposit Account

If there are any further charges not accounted for herein, please charge them to our deposit account No. 02-2666.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Dated: February 28, 2003

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X. APPENDIX A

The claims on appeal read as follows:

11. A catheter comprising:

a mandrel comprised of a variable stiffness, non-metal material, said mandrel uniformly tapered from a proximal section to a distal section, and said mandrel adapted to reinforce said catheter.

12. The catheter of claim 11 wherein said material is selected from the group consisting of: polyamides, PEEK, PPS, PEI, PI, and any combination thereof.

13. The catheter of claim 11 wherein a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel.

14. The catheter of claim 11 further comprising an inflatable member comprising a proximal portion and a distal portion, wherein said distal section of said mandrel extends past said proximal portion of said inflatable member.

15. The catheter of claim 14 wherein said distal section of said mandrel extends past said distal portion of said inflatable member.

16. The catheter of claim 11, wherein said mandrel is formed by annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

17. The catheter of claim 11, wherein said mandrel is formed by necking at high temperatures such that said proximal section is stiffer than said distal section.

18. The catheter of claim 11, wherein said mandrel is formed by taper extruding such that said proximal section is stiffer than said distal section.

19. A catheter comprising:

an outer member;

a hollow inner member extending through said outer member;

an outer lumen between said inner and outer members; and

a mandrel extending through said outer lumen, said mandrel comprised of a variable stiffness, non-metal material, said mandrel uniformly tapered from a proximal section to a distal section, and said mandrel is adapted to reinforce said catheter.

20. The catheter of claim 19 wherein said material is selected from the group consisting of: polyamides, PEEK, PPS, PEI, PI, and any combination thereof.

21. The catheter of claim 19 wherein a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel.

22. The catheter of claim 19 further comprising an inflatable member comprising a proximal portion and a distal portion, wherein said distal section of said mandrel extends past said proximal portion of said inflatable member.

23. The catheter of claim 22 wherein said distal section of said mandrel extends past said distal portion of said inflatable member.

24. The catheter of claim 19, wherein said mandrel is formed by annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

25. The catheter of claim 19, wherein said mandrel is formed by necking at high temperatures such that said proximal section is stiffer than said distal section.

26. The catheter of claim 19, wherein said mandrel is formed by taper extruding such that said proximal section is stiffer than said distal section.

39. An apparatus for reinforcing a catheter for insertion into a body lumen comprising:

a non-metal material mandrel for reinforcing said catheter comprising a proximal section and a distal section, said mandrel uniformly tapered from said proximal section to said distal section, and said mandrel being formed by necking at high temperatures such that said proximal section is stiffer than said distal section.

40. The apparatus of claim 39 further comprising an inflatable member with a proximal portion and a distal portion wherein said distal section of said mandrel extends past said proximal portion of said inflatable member.

41. The apparatus of claim 40 wherein said distal section of said mandrel extends past said distal portion of said inflatable member.

42. The apparatus of claim 39 wherein said mandrel is formed by necking at high temperatures and annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

43. The apparatus of claim 42 wherein said mandrel is formed by taper extruding such that said proximal section is stiffer than said distal section.

44. The apparatus of claim 39 wherein a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel.

45. An apparatus for reinforcing a catheter for insertion into a body lumen comprising:

a non-metal material mandrel for reinforcing said catheter comprising a proximal section and a distal section, said mandrel uniformly tapered from said proximal section to said distal section, and said mandrel being formed by annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

46. The apparatus of claim 45 further comprising an inflatable member with a proximal portion and a distal portion wherein said distal section of said mandrel extends past said proximal portion of said inflatable member.

47. The apparatus of claim 46 wherein said distal section of said mandrel extends past said distal portion of said inflatable member.

48. The apparatus of claim 45 wherein said mandrel is formed by annealing to induce a higher crystallinity and necking at high temperatures such that said proximal section is stiffer than said distal section.

49. The apparatus of claim 48 wherein said mandrel is formed by taper extruding such that said proximal section is stiffer than said distal section.

50. The apparatus of claim 45 wherein a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel.

51. An apparatus for reinforcing a catheter for insertion into a body lumen comprising:

a non-metal material mandrel for reinforcing said catheter comprising a proximal section and a distal section, said mandrel uniformly tapered from said proximal section to said distal section, and said mandrel being formed by taper extruding such that said proximal section is stiffer than said distal section.

52. The apparatus of claim 51 further comprising an inflatable member with a proximal portion and a distal portion wherein said distal section of said mandrel extends past said proximal portion of said inflatable member.

53. The apparatus of claim 52 wherein said distal section of said mandrel extends past said distal portion of said inflatable member.

54. The apparatus of claim 51 wherein said mandrel is formed by taper extruding and necking at high temperatures such that said proximal section is stiffer than said distal section.

55. The apparatus of claim 54 wherein said mandrel is formed by annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

56. The apparatus of claim 51 wherein a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel.

XI. APPENDIX B

57. (New) The catheter of claim 11, wherein said mandrel is fixed to a catheter shaft to lock said mandrel in place relative to said catheter.

58. (New) The catheter of claim 11, further comprising an inner tubular member disposed near said mandrel, wherein said inner tubular member is adapted to receive a guidewire.

59. (New) The catheter of claim 19, wherein said mandrel is fixed to a catheter shaft to lock said mandrel in place relative to said catheter.

60. (New) The catheter of claim 19, wherein said hollow inner member is adapted to receive a guidewire.

61. (New) The apparatus of claim 39, wherein said mandrel is fixed to said catheter to lock said mandrel in place relative to said catheter.

62. (New) The apparatus of claim 39, further comprising an inner tubular member disposed within said catheter and adapted to receive a guidewire.

63. (New) The apparatus of claim 45, wherein said mandrel is fixed to said catheter to lock said mandrel in place relative to said catheter.

64. (New) The apparatus of claim 45, further comprising an inner tubular member disposed within said catheter and adapted to receive a guidewire.

65. (New) The apparatus of claim 51, wherein said mandrel is fixed to said catheter to lock said mandrel in place relative to said catheter.

66. (New) The apparatus of claim 51, further comprising an inner tubular member disposed within said catheter and adapted to receive a guidewire.